



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

516891

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

WARNING LETTER

VIA FEDERAL EXPRESS

August 24, 2001

Our Reference Number: 2954854/3003154172

Mr. Rod McLeod,  
President and Chief Operating Officer  
United States Lines  
5835 Blue Lagoon Drive, Third Floor  
Miami, FL 33126

Dear Mr. McLeod,

On August 18, 2001, U.S. Food and Drug Administration (FDA) Investigators Randall Zielinski and Janice Gardner conducted an inspection of your vessel, the *MS Patriot*, while it was berthed at Pier 10-11 in Honolulu, Hawaii. The inspection was conducted under the authority of Section 361 of the Public Health Service Act and the Federal Food Drug, and Cosmetic Act, as amended. The inspection revealed significant deviations from the federal regulations for good manufacturing practices (GMPs) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110), and the Interstate Conveyance Regulations (21 CFR 1250). Observations made by the investigators were listed on Inspectional Observations (Form FDA 483), the Food Service Establishment Inspection Record (Form FDA 2420), and the Inspection Summary - Vessel Sanitation (Form FDA 2432), copies of which were provided to, and discussed with, Mr. Gordon Schenk, Vice President, at the conclusion of the inspection. Copies of these forms are enclosed with this letter.

The inspectors' observations include the following:

- Foods, stored more than four inches deep in containers in the refrigerator, exceeded acceptable temperature limits (mahi-mahi prepared at 6AM was measured at 51° F at 10:30AM, shrimp prepared before 7AM was measured as 54° F at 10:15AM);
- Ham sliced in the early morning and used to prepare sandwiches was measured at 51° F;
- Cooked fish was stored under raw fish and rack of lamb was stored next to raw chicken in the refrigerator;

- Two containers of cooking oil were not labeled;
- The chute of the ice machine on Deck A was moldy and deteriorated;
- The dishwashing area tables and rack fail to drain properly; there is a buildup of food debris and cloudy water under the dish machine conveyor;
- There was no measurable chlorine in the dishwashing machines in Digby's and the Eagle's Watch pantry;
- Cutting boards in the bar area and the butcher shop were greasy and dirty with mold;
- The floor drain troughs in the tilt skillet and jacketed steam kettle area do not empty and there was a strong sewer odor;
- The vegetable freezer had a large ice build-up on the floor under the refrigerator coils;
- There was no hand soap at the sink in the fish preparation room;
- There was standing water on the floors in the hot food and dish areas of the Outrigger pantry;
- Walls have holes where equipment has been removed and where panels are dented in the galley area;
- A large plastic container of an unlabeled cleaner was found in the chemical storeroom.

The insanitary conditions and practices found aboard your vessel are likely to result in adulteration of foods within the meaning of 402(a)(1), 402(a)(3), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Adulteration of food while held for sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act. The delivery or causing the delivery of adulterated foods into interstate commerce is prohibited by Section 301(a) of the Act.

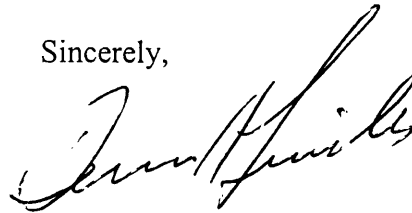
In consequence of the inspectional findings, your operation has been assigned a "Provisional" classification. If the cited deficiencies are not corrected within thirty (30) days from the receipt of this notification, your facility will be placed on "Not Approved" status. Assignment of "Not Approved" status means you cannot provide food service from this vessel until the violations have been corrected and the vessel has been reinspected by FDA.

You should notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct and prevent a recurrence of the cited deficiencies. Your response should be directed to:

Randall Zielinski, CSO/ITS  
U.S. Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6702.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley  
District Director  
San Francisco District

Cc: VIA FEDERAL EXPRESS  
Phil Calian, Chief Executive Officer  
American Classic Voyages Co.  
2 North Riverside Plaza, Suite 200  
Chicago, IL 60606

Cc: VIA FEDERAL EXPRESS  
Gordon Shenk, Vice President Hotel Operation  
United States Lines – MS Patriot  
700 Bishop Street  
Honolulu, HI 96813

Enclosures:

List of Inspectional Observations (FDA Form 483)  
Food Service Establishment Inspection Record (Form FDA 2420)  
Inspection Summary - Vessel Sanitation (Form FDA 2432)